Global Safety & Risk Assessment Protocol for New Genomic Technologies

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I. Truly Responsible Use

The environmental release and widespread production and consumption of genetically modified organisms (GMOs) since the mid-1990s has raised serious ecological, human health, and socioeconomic concerns. More recently, the advent, wide accessibility, and relative speed of new genomic techniques (NGTs) has brought humans into a new era of genetic change such as we have never before experienced. For some, these new technologies are seen as a potential opportunity to benefit humanity through the introduction of new varieties to farming and food systems, carrying traits that are intended to address health and/or environmental challenges. The power of these new techniques however carries risks that, if not carefully addressed, may cause unintended effects across ecosystems and communities[2].

This brief document proposes guidance for a globally adoptable risk assessment protocol and associated code of ethics for safer development and environmental release of organisms created through all types of genetic engineering. All governments are encouraged to adopt the components of this Protocol into their respective regulatory frameworks in order to bring a globally harmonized approach for regulating genetic engineering and thereby better assure a safe food supply that is managed in an environmentally prudent manner.

A fundamental premise of this Risk Protocol is that it is the act of human intervention through specific engineering techniques – as opposed to any naturally occurring genetic changes not caused by human interventions – that determine the scope of activities that this Risk Protocol is meant to encompass.

This Risk Protocol must be taken as a holistic set of criteria and actions. Failure to adequately address all criteria as described may undermine the objectives of environmental stability and health intended by this Protocol. Partial compliance shall therefore not be an acceptable outcome.

II. Ethics

The following tenets and actions underlie all activities with respect to genetic engineering in all of its forms and uses:

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[1] All stakeholders are invited to comment on and improve this document. Please send all feedback to seeds@ifoam.bio.

[2] Key definitions and an indicative list of applicable techniques may be found in the IFOAM – Organics International Position Paper on the Compatibility of Breeding Techniques in Organic Systems - https://www.ifoam.bio/sites/default/files/2020-03/Breeding_position_paper_v01_web_0.pdf.

1. Notification of Intent & Purpose

Any and all plans to develop, via genetic engineering techniques, genomes that are intended for environmental release or otherwise for open market distribution, at any time in the present or future, shall be publicly announced and made known to applicable government authorities as to the intended outcomes posed by the new genome.

Notification shall include:

- a description of the intended product(s), the changes intended by/through them;
- their anticipated uses and benefits;
- the techniques to be used; and
- an indication of the location where the first environmental introduction(s) may occur.

Additional proposed plans for development and release such as are enumerated in sections below may be divulged at this time as well, to the extent that they are known. The developer shall provide adequate time to enable stakeholders to raise concerns to the developer and relevant regulatory authorities at least with respect to adequate controls and risk mitigation measures such as are enumerated in this Risk Protocol document. Developers shall adjust their plans accordingly and make them transparent prior to the undertaking of the engineering activities.

2. Assessment and Risk Mitigation of Unintended Consequences

Based on the developer's own forecast as well as concerns raised by stakeholders regarding unintended consequences of the genetic engineering, developers shall describe how they intend to mitigate risks posed by unintended effects of their activities. Such compensatory measures shall likewise be consulted with stakeholders and an iterative process conducted with them, with the aim of achieving informed consent to proceed with the proposed genetic engineering techniques. Where consensus[3] among stakeholders is not possible to achieve, the developer shall at least be able to reasonably demonstrate that all of the aspects described in the Risk Protocol have been sufficiently addressed[4].

3. Accessibility of Information regarding Intended Genomic Changes

Users of genetic engineering technologies shall make their genomes available to relevant stakeholders for the purposes of detection, analysis and phenotypic study as a means to support the safe introduction and ongoing acceptability of such new genomes to the environment, agriculture, and food systems (as well as for non-food uses). In particular, such materials shall be made available prior to environmental release and commercialization. Applicable intellectual property rights shall be respected while enabling researchers and regulatory bodies access to these genome(s) and the naturally-sourced reference genome(s) from which they have been derived.

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[3] Consensus is defined as the absence of sustained objection.

[4] Refer also to:
FAO. 2023. Gene editing and food safety – Technical considerations and potential relevance to the work of Codex Alimentarius. Rome. https://doi.org/10.4060/cc5136en

All developments using genetic engineering undertaken within a given country should be collated and shareable through a nationally-maintained registry and database that shows key information about such genomes under development, including field trials and wider environmental or other commercial/market presence. All developers must share their data accordingly. Such data may include but not be limited to the following: name and location of developer; genome(s) being developed; stage of development (eg laboratory stage, field trial, commercial release); incidents of concern; legal authorization(s) and/or penalties; studies undertaken (with associated links); and links to records of stakeholder engagement and consultations with them. Access to said database should be free and open to any stakeholder in any jurisdiction. To avoid frivolous interventions, stakeholders may be asked to register or qualify their particular interest, for example by identifying their role(s), interest in particular crop(s) or techniques, organizational association, etc.

4. Patents and intellectual property rights

Thousands of patents have been claimed to date on methods and products of genetic engineering, including new technologies such as genome editing. Patents on plant or animal genetic material expose all actors in the food supply chain to significant legal uncertainty as to what they can or cannot do with the plants and animals they work with on a daily basis. Access to plant breeding material is correspondingly significantly restricted. The increasing number of patents on specific traits and genetic material or information is a threat to innovation in the breeding sector, which relies on a wide circulation of genetic material.

Patents can cover products such as plants or cells through product-by-process claims, not just the technology itself. Patent claims have been made that cover all cells, seeds and plants containing the same introduced (ie non-native) genetic sequence, from a long list of crop species, ranging from broccoli to maize, soybean, rice, wheat, cotton, barley, and sunflower. In this sense, patents do not only cover technology but also traits and biological material in general, as long as a technical process was involved, even if it previously occurred in nature. More problematically, often the coverage of such patents not only includes plants produced with genetic engineering but also such from breeding through biological methods[5].

This poses a high risk of consolidation and monopolization of genetic resources and patent thickets[6] in the seed sector that eventually could put most breeding to a halt[7]. NGTs shall therefore be excluded from patentability and instead plant variety protection shall be used to protect the intellectual property of the breeder. Furthermore, products that have been bred through biological methods or are based on biological material without the use of the material of the patent holder shall be excluded from any patent claims.

[5]https://www.global2000.at/sites/global/files/GLOBAL2000_NeueGentechnik_Patente_Report_20221019.pdf

[6]https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/312540/informatic-thickets.pdf

[7] https://www.mdpi.com/2073-4395/11/6/1218

5. Allow for GMO-free regions

Developers of the products of genetic engineering techniques must respect the existence of established GMO-free regions and not undertake their activities in a manner that deliberately encroaches on such regions.

III. No-go areas

No Gene Drives

Gene drives carry unforeseeable risks to ecosystem balance and interspecies relationships. As such, they shall not be allowed for any environmental release.

No Drugs into Food Plants

Ample historical evidence of unintended genetic pollution of traditional varieties due to uncontrolled environmental releases and/or inadvertent contamination of seed stocks or supply chains demands that, in order to protect human and animal health, no crops shall be engineered to produce pharmaceutical components not otherwise naturally found in that variety.

IV. Phenotyping & Detectability

In the developmental stages of engineering new genomes it is vital to assure that intended effects manifest in a precise, consistent and stable manner, and that unintended negative effects are avoided. Basic criteria for increasing confidence in these outcomes include but are not limited to the following:

- A method to identify and analytically detect the newly engineered genome compared to the variety from which it was derived. Such method(s) shall be made publicly known.
- A comparison through genetic sequencing of the new genome with the reference genome from which it is derived. Off-target changes in the DNA and/or RNA sequence(s) of the new genome must be identified and their resulting phenotypic expression identified and reported, with subsequent evaluation enabled through a multistakeholder process.

Analysis of genomes newly developed through genetic engineering techniques, and their respective phenotypic analyses, must occur through a transparently divulged sampling methodology showing statistically significant and consistent results.

The above activities must be conducted by the developer and shall be reproducible and affirmed by a competent impartial third party.

V. Pre-market Environment

Development and pilot/trial production of the genetically engineered variety must occur in isolation from the larger environment. Measures to assure that the manipulation of germplasm and its initial production cycles must be done such that there is not a risk of escape of the organism and/or any adoption of its genetic components (eg pollen) by other varieties or species, until such time as risks of unintended effects have been minimized in line with this Risk Protocol.

In addition to the assessments specified in section IV above, the trial production environment shall include a plan to assess the effects of the new variety on ecosystem balance, biodiversity, animal (livestock) health and welfare, and human health. A plan to address intra-organism, inter-organism, and ecosystem-wide effects shall be presented to stakeholders, whose feedback shall be taken into account to adjust the pilot production plans accordingly.

Any escape or otherwise unintended release or unintended effects arising during the trial production period shall be alerted to stakeholders, with a description of all mitigation measures taken in response and their effectiveness to limit risk or otherwise unintended consequences, and all known means to trace and isolate the new variety from further migration into the ecosystem or stream of commerce.

The results of trial production shall be made known to stakeholders, addressing all factors as mentioned in this Risk Protocol. Proceeding to larger scale production shall only occur following the adequate address of concerns raised by stakeholders through a due process overseen by applicable regulatory authorities.

VI. Disclosure, Labeling, and Claims

All products of genetic engineering shall be disclosed so that regulatory oversight is enabled and consumers can make informed choices. Labeling shall transparently and clearly divulge in commonly understandable terminology the changes made through the genetic engineering. Regardless of the type of consumer, the product they obtain must be labeled to identify the engineered species or derivatives thereof that are contained in the product, whether or not it still contains the modified genetic material.

Claims regarding the distinctive attributes brought by the engineered variety shall be limited to the specific resultant genetic and phenotypic changes (both intended and unintended) and related measurable effects, without any further subjective implications on environmental sustainability or health.

VII. Monitoring

The effects and performance of engineered genomes shall be monitored for a minimum of ten years following the initial environmental release, and shall heed all relevant regulatory requirements, criteria and concerns raised by stakeholders during consultative processes conducted in line with this Risk

Protocol. Monitoring reports shall be accessible publicly and shall provide stakeholders with a means of redress.

VIII. Liability

Liability for trespasses, material damage, and/or economic or other losses to other individual parties or market sectors (such as to the reputation of the integrity of the organic market) shall be the responsibility of the party who initially places the new variety on the market, or who otherwise causes damages through premature environmental release. Liability may be assigned retroactively in cases where risk was not adequately assessed prior to release.

Regions or other jurisdictions that have been declared GM-free (or similar) may refuse and bar the development, trial or broader environmental release of a genetically-engineered genome within their jurisdiction. Such jurisdictions, if adversely affected as to their status as GM-free zones because of incursion by genetically engineered varieties may exercise their right to fair economic compensation.